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EXAMINER	
LEE, JAE W	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,536	LOCKERBIE ET AL.	
	Examiner	Art Unit	
	Jae W. Lee	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *8 and 11-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :04/08/2004, 10/16/2006, 01/08/2007.

DETAILED ACTION

Application status

Claims 1-23 are pending in this application.

Preliminary amendments for claims, filed on 11/07/2006, is acknowledged.

Priority

A claim of priority to the U.S. Non-Provisional Application No. 10/377,524, filed on 02/28/2003, U.S. Non-Provisional Application No. 09/586,147, filed on 06/02/2000, U.S. Provisional Application No. 60/319,488, filed on 08/23/2002, and U.S. Provisional Application No. 60/319,641, filed on 10/22/2002, is acknowledged.

Election

Applicant's election without traverse of Group I, claims 1-10 and 20-23, is acknowledged. Further, Applicant's election of the blood component comprising platelets is acknowledged. Applicant's assumption that claim 10 should be included in Group I is acknowledged. Applicants have withdrawn claims 8 and 11-19 as being drawn to a non-elected invention.

Therefore, claims 1-7, 9, 10 and 20-23 with those methods comprising fluids comprising platelets, not platelets themselves, will be examined on the merits, and claims 8 and 11-19 are withdrawn from further consideration.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claim 5 is objected to because of the following informalities:

Claim 5 is objected to because the recitation of "TPGS" should be in parenthesis and follow the phrase it abbreviates when used for the first time.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9, 10 and 20-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (2-7, 9, 10 and 20-23 dependent therefrom) recites the phrase, "substantially maintaining damage to pathogen nucleic acid," which is unclear. It is

indefinite and unclear because "substantially maintaining" is confusing with respect to how long it has to substantially maintain damage.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9, 10 and 20-23 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7, 9, 10 and 20-23 are directed to a process for maintaining damage to pathogen nucleic acid in a fluid containing any pathogens and any blood components comprising steps of: adding to the fluid any photosensitizer comprising riboflavin; irradiating the fluid and any photosensitizer with light at any wavelength to activate any photosensitizer to cause any damage to pathogen nucleic acid; substantially maintaining any damage to pathogen nucleic acid; and wherein any damage to pathogen nucleic acid caused by any photosensitizer and any light is substantially maintained during storage of the fluid after irradiation.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of [compositions or methods], it must be clear that: (1) the identifying

characteristics of the claimed [compositions or methods] have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The specification discloses an example of a process comprising steps of: adding to a solution containing platelets, 50 μM of isoalloxazine photosensitizer comprising riboflavin; irradiating a solution containing platelets, 10^6/mL Jurkat cells and 50 μM of isoalloxazine photosensitizer with light, at wavelength of 320 nm and intensity of 7 J/cm^2, to activate isoalloxazine photosensitizer to cause single strand and double strand breaks to the pathogen deoxyribonucleic acids and ribonucleic acids; substantially maintaining said strand breaks to said pathogen deoxyribonucleic acids and ribonucleic acids; and wherein said strand breaks caused by the isoalloxazine photosensitizer and light, at wavelength of 320 nm and intensity of 7 J/cm^2, is substantially maintained during storage of a solution containing platelets, 10^6/mL Jurkat cells and 50 μM of isoalloxazine photosensitizer after irradiation. This is an inadequate written description for a process for maintaining any damage to pathogen nucleic acid in a fluid containing any pathogens and any blood components comprising steps of: adding to the fluid any photosensitizer comprising riboflavin; irradiating the fluid and any photosensitizer with light at any wavelength to activate any photosensitizer to cause any damage to pathogen nucleic acid; substantially maintaining any damage to pathogen nucleic acid; and wherein any damage to pathogen nucleic acid caused by any photosensitizer and

any light is substantially maintained during storage of the fluid after irradiation (see Examples 1-3 on pg. 9-13) because the specification lacks description with respect to structures and/or functional properties related to those structures of any "damage", any "pathogen", any "blood component", any "photosensitizer", and any "light".

In addition, the specification describes said process as mentioned above, wherein *E. coli* (see Example 4 on pg. 13) or *E. coli* containing lambda-phage virus (see Example 5 on pg. 13 and 14) was added before the irradiation. However, this is an inadequate description with respect to claimed process using any pathogen.

Further, the specification lacks description with respect to the process of claim 2 comprising substantially maintaining the damage to any pathogen nucleic acid after transfusion into a recipient, and there is not even a single example of such claimed process.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-7, 9, 10 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for a process comprising steps of: adding to a solution containing platelets, 50 μM of isoalloxazine photosensitizer comprising riboflavin; irradiating a solution containing platelets, 10^6/mL Jurkat cells and 50 μM of isoalloxazine photosensitizer with light, at wavelength of 320 nm and intensity of 7 J/cm^2, to activate

isoalloxazine photosensitizer to cause single strand and double strand breaks to the pathogen deoxyribonucleic acids and ribonucleic acids; substantially maintaining (see also the 112 2nd paragraph rejection above) said strand breaks to said pathogen deoxyribonucleic acids and ribonucleic acids; and wherein said strand breaks caused by the isoalloxazine photosensitizer and light, at wavelength of 320 nm and intensity of 7 J/cm^2, is substantially maintained during storage of a solution containing platelets, 10^6/mL Jurkat cells and 50 μM of isoalloxazine photosensitizer after irradiation, further wherein *E. coli* or *E. coli* containing lambda-phage virus was added before the irradiation instead of the Jurkat cells, does not reasonably provide enablement for a process for maintaining any damage to pathogen nucleic acid in a fluid containing any pathogens and any blood components comprising steps of: adding to the fluid any photosensitizer comprising riboflavin; irradiating the fluid and any photosensitizer with light at any wavelength to activate any photosensitizer to cause any damage to pathogen nucleic acid; substantially maintaining any damage to pathogen nucleic acid; and wherein any damage to pathogen nucleic acid caused by any photosensitizer and any light is substantially maintained during storage of the fluid after irradiation. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some

experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Claims 1-7, 9, 10 and 20-23 are so broad as to encompass a process for maintaining any damage to pathogen nucleic acid in a fluid containing any pathogens and any blood components comprising steps of: adding to the fluid any photosensitizer comprising riboflavin; irradiating the fluid and any photosensitizer with light at any wavelength to activate any photosensitizer to cause any damage to pathogen nucleic acid; substantially maintaining any damage to pathogen nucleic acid; and wherein any damage to pathogen nucleic acid caused by any photosensitizer and any light is substantially maintained during storage of the fluid after irradiation.

The specification does not support the broad scope of the claimed process comprising steps of: adding to all fluids, all modifications and derivatives of all photosensitizers comprising riboflavin; irradiating all fluids and all photosensitizers with light at all wavelengths to activate all photosensitizers to cause all damages to all pathogen nucleic acids; substantially maintaining all damages to all pathogen nucleic acids; and wherein all damages to all pathogen nucleic acid, caused by all photosensitizers and all lights at all wavelengths and all intensities, is substantially maintained during storage of all fluids after irradiation because the specification does not establish: (A) adequate guidance with respect to practicing the claimed process with all pathogens; (B) guidance with respect to all modifications and derivatives of all photosensitizers comprising riboflavin; (C) guidance with respect to practicing the claimed process using all types of fluids including but not limited to liquids (i.e. hydrophobic solvent, aqueous solvent, organic media and etc), gases and plasmas (D) adequate guidance with respect to practicing the claimed process using the light at all wavelengths and all intensities; (E) guidance with respect to practicing the claimed process that results in all types of nucleic acid damages including but not limited to deaminations, free-radical induced oxidations, single or double strand breaks, interstrand and intrastrand crosslinks, methylations, alkylations, intercalations and etc; (F) guidance with respect to practicing the claimed process that can maintain the damage caused to the pathogen nucleic acid for an unspecified duration" (see above 112 2nd paragraph rejection under "substantially maintaining...); (G) any guidance with respect to practicing the claimed process that substantially maintains the damage to the

pathogen nucleic acid after transfusion into a recipient; and (H) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Because of this lack of guidance, it would require undue experimentation for one skilled in the art to make and use a process for maintaining any damage to pathogen nucleic acid in a fluid containing any pathogens and any blood components comprising steps of: adding to the fluid any photosensitizer comprising riboflavin; irradiating the fluid and any photosensitizer with light at any wavelength to activate any photosensitizer to cause any damage to pathogen nucleic acid; substantially maintaining any damage to pathogen nucleic acid; and wherein any damage to pathogen nucleic acid caused by any photosensitizer and any light is substantially maintained during storage of the fluid after irradiation.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 6, 7, 10, 20, 21 and 23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Goodrich et al. (USPN 6,258,577).

Claims 1, 3, 6, 7, 10, 20, 21 and 23 are directed to a process for substantially maintaining damage to pathogen nucleic acid in a fluid containing pathogens and blood components comprising the steps of: adding to the fluid a photosensitizer comprising riboflavin; irradiating the fluid and photosensitizer with light at an appropriate wavelength to activate the photosensitizer to cause damage to the pathogen nucleic acid; substantially maintaining the damage to the pathogen nucleic acid; and wherein the damage to pathogen nucleic acid caused by the photosensitizer and light is substantially maintained during storage of the fluid after irradiation.

It is noted that the Examiner's interpretation of "a photosensitizer comprising riboflavin" is based on the Applicant's disclosure on pg. 6 of the specification as follows:

> "Examples of such endogenous photosensitizers which may be used in this invention are alloxazines such as 7,8-dimethyl-10-ribityl isoalloxazine (riboflavin), 7,8,10-trimethylisoalloxazine (lumiflavin), 7,8-dimethylalloxazine (lumichrome), isoalloxazine-adenine dinucleotide (flavine adenine dinucleotide [FAD]) and alloxazine mononucleotide (also known as flavine mononucleotide [FMN] and riboflavine-5-phosphate),"

therefore, alloxazines and isoalloxazines are interpreted to be within the scope of "a photosensitizer comprising riboflavin."

Goodrich et al. teach a method and apparatus for inactivation of biological contaminants using riboflavin analogues, alloxazine or isoalloxazine, as photosensitizers. Goodrich et al. specifically teach a method for decontamination of a fluid, by inactivation of microorganisms therein, sufficiently effective such that said fluid can be administered to a patient, said fluid also containing a component selected from the group consisting of biologically active protein, blood, and blood constituents, without destroying the biological activity of such component, said method comprising: (a) adding an effective, non-toxic amount of an endogenous alloxazine or isoalloxazine photosensitizer (see above Examiner's interpretation) to said fluid; (b) exposing the fluid of step (a) to photoradiation or light sufficient to activate the endogenous photosensitizer; and (c) allowing said activated endogenous photosensitizer to inactivate said microorganisms, thereby anticipating Applicant's Claim 1, 3 and 7 (see column 23). Goodrich et al. also teach an extracorporeal method for decontamination of whole blood using apparatus shown in Figure 6 and 7, by inactivation of microorganisms therein, such that said blood can be administered or transfused back into a patient, wherein the damage to the pathogen nucleic acid is maintained, without destroying the biological activity of protein, blood, and blood constituents, said method comprising: (a) adding to blood an effective, non-toxic amount of an endogenous alloxazine or isoalloxazine photosensitizer which inactivates microorganisms in the presence of albumin; (b) exposing the fluid of step (a) to photoradiation sufficient to

activate the endogenous photosensitizer; and (c) allowing said activated endogenous photosensitizer to inactivate said microorganisms, thereby anticipating Applicant's Claim 21 (see Figures 6 and 7, and columns 11, 12 and 24). Goodrich et al. also teach that isoalloxazine photosensitizer was used at concentrations of 1, 50 and 100 μM (see column 19), thereby anticipating Applicant's Claims 10 and 23. Goodrich et al. further teach that an anticoagulant is added to said fluid to enhance blood component viability, thereby anticipating Claim 6 (see column 24). Goodrich et al. also teach that their method is used with platelets, and virus in Example 6, thereby anticipating Claim 20. Therefore, Goodrich et al. anticipate the Applicant's process for substantially maintaining damage to pathogen nucleic acid in a fluid containing pathogens and blood components comprising the steps of: adding to the fluid a photosensitizer comprising riboflavin; irradiating the fluid and photosensitizer with light at an appropriate wavelength to activate the photosensitizer to cause damage to the pathogen nucleic acid; substantially maintaining the damage to the pathogen nucleic acid; and wherein the damage to pathogen nucleic acid caused by the photosensitizer and light is substantially maintained during storage of the fluid after irradiation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9, 10 and 20-23 are rejected on the ground of nonstatutory double patenting over claims 1-18 of U. S. Patent No. 6,258,577 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method for decontamination of a fluid, by inactivation of microorganisms therein, sufficiently effective such that said fluid can be administered to a patient, said fluid also containing a component selected from the group consisting of biologically active protein, blood, and blood constituents, without destroying the biological activity of such component, said method comprising: (a) adding an effective, non-toxic amount of an endogenous alloxazine or isoalloxazine photosensitizer to said fluid; (b) exposing the fluid of step (a) to photoradiation sufficient to activate the endogenous photosensitizer; and (c) allowing said activated endogenous photosensitizer to inactivate said microorganisms. The claims 1-7, 9, 10 and 20-23 in

the instant application are fully anticipated by the disclosure of U.S. Patent No. 6,258,577 which was granted to one of the identical inventors of this instant application.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

Claims 1-7, 9, 10 and 20-23 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner: Jae W. Lee, Ph.D.

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER